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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/546,143	04/10/00	MATZINGER	P 9473

HM22/0907

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EXAMINER	
TRUONG, T	
ART UNIT	**PAPER NUMBER**
1624	3

DATE MAILED: 09/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/546,143	Applicant(s) Matzinger Er. Al.
	Examiner Tamthom N. Truong	Group Art Unit 1624

☒ Responsive to communication(s) filed on *Apr 10, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *10-27* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *10, 11, and 27* is/are allowed.

☒ Claim(s) *12, 14, 15, 17, 19, 21, 23, 25, and 26* is/are rejected.

☒ Claim(s) *13, 16, 18, 20, 22, and 24* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) *08/832,253*.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

FIRST ACTION ON MERIT

Applicants' preliminary amendment filed on 4-10-00 is acknowledged. Accordingly, with claims 1-9 canceled, only claims 10-27 are considered herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 14, 15, 17, 19, 21, 23, and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds wherein R^4 is a tert-butyl ester, tert-butyl carboxylate, or tert-butoxycarbonyl, does not reasonably provide enablement for the genera with R^4 as another functional group serving as a **"protecting group"**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The disclosure does not provide guidance as to what functional groups, and/or rings can be considered as a protecting group. Its mere statement *"R^4 is a protecting group, preferably a tert.-butoxycarbonyl group"* is insufficient for one skilled in the art to consider what other groups can be a "protecting group". In considering enablement, undue experimentation is an important factor. Here, the scope of "protecting group" is undoubtedly broad, and the generic teaching for preparation only gears toward one protecting group, namely tert.-butoxycarbonyl. Thus,

regarding other groups, one skilled in the art will have to carry out undue experimentation as the chemical art is unpredictable. Note, the Federal Circuit has repeatedly held that **"the specification must teach those skilled in the art how to make and use the** *full scope of the claimed invention* **without 'undue experimentation'"** (see **In re Wright**, 999 F.2d 1557, 1561, 27 U.S.P.Q. 2d 1510, 1513 (Fed. Cir. 1993)). Also, the disclosure does not provide the starting material for R^4, nor a source for a "protecting group", and thus, undue experimentation is inevitable for one skilled in the art to make and use compounds with R^4 as a group other than tert.butoxycarbonyl. See In re Howarth, 210 USPQ 689, 693 regarding insufficient enablement. Note, in said case, the starting material was not disclosed, nor was a source named. The court, then, ruled that "**burden rests upon applicant who chooses to rely upon general knowledge in art to render his disclosure enabling to establish that those of ordinary skill in art can be expected to possess or know where to obtain this knowledge;...**" Thus, no starting materials disclosed for how to make a compound is a sound reason to render a specification with insufficient enablement. Applicants are advised to amend claims in commensurate with the scope of enablement provided by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 14, 15, 17, 19, 21, 23, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Said claims recite the limitation of "protecting group" which has no description in the specification other than "tert.-butoxycarbonyl", a sole representative of said group. Thus, one skilled in the art cannot ascertain what other groups can be considered as a "protecting group". Therefore, the metes and bound of the invention is indefinite.

2. The definition of R^1 is missing in claim 25.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim 23 is rejected under 35 U.S.C. **102(a)** as being anticipated by **Lampe et. al.** (J. Org. Chem., 1996, 61(14), 4572-4581). On page 4575, Lampe et. al. disclose an intermediate (compound 25) which is embraced by formula X in claim 23 with R^4 as a protecting group.

Claims 17, 23, and 25 are rejected under 35 U.S.C. **102(b)** as being anticipated by the following references:

Krogsgaard-Larsen et. al. (Acta Chemica Scandinavica B, 32 (1978) 327-334):

Compounds 12 and 13 on page 328 are embraced by formula VIII in claim 17 with R^3 as a lower alkyl and R^4 as a protecting group.

Adams et. al. (J. Chem. Soc. Perkin Trans. 1, 1995, 2355-2362): On page 2356, compound 20 is embraced by formula X in claim 23, and compound 21 is embraced by formula XI in claim 25 since R^1 is undefined, and R^4 is simply a protecting group.

Claim 25 is rejected under 35 U.S.C. **102(e)** as being anticipated by **Barbier et. al.** (US 5,583,222 or US'222). Compounds B1 - B23 listed on columns 18 - 21 are embraced by formula XI in claim 25 for reasons aforementioned.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barbier et. al.** (US'222). On column 9, Barbier et. al. disclose a group of intermediates represented by formula III which resembles the claimed formula XI since variable Y of the reference can be taken as NH while -CO-A corresponds to the claimed variable R^4, a protecting group. Although Barbier et. al. do not have an example of making a species as recited in claim 26, said species can be envisaged from the reference's formula III because the definitions of A and R^{16} of formula III permit an azepane substituted with (4-lower alkoxy-benzoylamino) and tert.-butoxycarbonyl (or tert.-butyl carboxylate). Moreover, with respect to genus-species situations, the M.P.E.P. states that **"a generic chemical formula will** *anticipate* **a claimed species covered by the formula when the species can be** *"at once envisaged"* **from the formula."** (M.P.E.P. 2131.02) Such an issue of patentability has also been decided by the court in In re Susi, 440 F 2d. 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. v. Biocraft Laboratories, 874 F 2d. 804, 10 USPQ 2d. 1843, 1846 (Fed. Cir. 1989), and In re Swinehart, 169 USPQ 225, 229 (CCPA 1971).

Claim Objections

Claims 13, 16, 18, 20, 22, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Allowable Subject Matter

Claims 10, 11, and 27 are allowable as references of record do not teach or fairly suggest formula IV and its species in claims 10 and 11, nor do they teach a compound rectied in claim 27..

A downloadable program is now available at this web site: **http://www.uspto.gov/printefs**, for applicants to print their own bibliographic information to avoid the need for corrected filing receipts.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mrs. Tamthom (or Tam) Truong whose telephone number is (703) 305 - 4485. The examiner can normally be reached on Monday thru Thursday from 7:30 am to 6:00 pm EST.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 - 1235 or 305 - 3290.

T. Truong / 9-5-00

Mukund J. Shah

Mukund J. Shah

Supervisory Patent Examiner

Art Unit 1624